I. The Office Action

The August 5, 2009 final office action (the "Office Action") in this application:

1.) rejects claims 1-3, 10-17, 19-20 and 29 under 35 U.S.C. 103(a); and

2.) rejects claims 1-20 and 29 under 35 U.S.C. 103(a).

Applicants respond as follows and hereby petition for a three-month extension of time to reply to the Office Action as well as submit a Request for Continued Examination (RCE), along with this response and amendments made to the claims, as detailed below.

II. Amendments to independent claims 1, 9 and 16

By the amendments, Applicants do not acquiesce to the propriety of any of the Examiner's rejections and do not disclaim any subject matter to which Applicants are entitled. By this amendment to all of the independent claims, all of the instant claims are hereby all directed to intradermal administration, support for this recitation can be found, for example, at least at page 27, line 29 and page 32, line 18 of the specification.

III. Rejection of claims 1-3, 10-17, 19-20 and 29 under 35 U.S.C. 103(a)

The Office Action has rejected claims 1-3, 10-17, 19-20 and 29 under 35 U.S.C. 103(a) as being unpatentable over Schim in view of Johnson et al. Office Action, page 3. Applicants respectfully traverse this rejection.

To maintain a proper rejection under 35 U.S.C. §103, the Office must establish a prima facie case of obviousness. Accordingly, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process.

Without acquiescing to the accuracy or propriety of the rejections, instant independent claims 1, 9 and 16 have been amended to specify that, to a specific patient that suffers from an acute pain medication overuse disorder caused by

overuse of acute pain medication, where the patient specifically takes the acute pain medication prior to experiencing pain and experiences pain after the intake of acute pain medication, the claimed method recites the method step of local intradermal administration of a pure botulinum toxin having a molecular weight of about 150 kDa to the patient with acute pain medication overuse disorder to thereby treat the acute pain medication overuse disorder caused by the overuse of acute pain medication. A review of Schim does not disclose the instant claim limitations, or even suggest the use of pure botulinum toxin having a molecular weight of about 150 kDa, as recited in the instantly claimed methods. There is no suggestion in this reference that one of ordinary skill in the art may point out or rely on that would direct one to the use of the instantly claimed pure botulinum toxin having a molecular weight of about 150 kDa to treat an acute pain medication overuse disorder. The Office Action at page 3 stated that Schim does not teach pure botulinum toxin. As such and based on Schim, there is no basis for one to then go beyond and consider the use of a pure botulinum toxin having a molecular weight of about 150 kDa, as presently claimed.

In order to supplement this lack of disclosure/teaching of the use of a pure botulinum toxin having a molecular weight of about 150 kDa (Office Action, page 3), the Office then turns to and applies Johnson et al., and combines its teachings with those of Schim. A review of U.S. Patent Number 5512547 reveals pharmaceutical compositions that include pure botulinum neurotoxin. As stated in the Office Action on pages 3-4, the pure toxin compositions of Johnson et al. have long term stability/shelf life at temperatures above 0^{o} C, however, the discussion of long shelf life of the pure botulinum toxin compositions discussed in Johnson et al. or the lessening of the possibility of antibody formation after injection in a patient, does not supplement the lack of teaching of Schim of local intradermal administration of a pure botulinum toxin having a molecular weight of about 150 kDa to the patient with acute pain medication overuse disorder to thereby treat the acute pain medication overuse disorder caused by the overuse of acute pain medication, where the patient specifically takes the acute pain

medication prior to experiencing pain and experiences pain after the intake of acute pain medication, as claimed.

Thus, Johnson et al. and Schim, alone or in any combination do not teach or suggest a method for treating an acute pain medication overuse disorder caused by overuse of acute pain medication where the method comprises the specific step of local intradermal administration of a pure botulinum toxin, wherein the pure botulinum toxin has a molecular weight of about 150 kDa, to a patient with acute pain medication overuse disorder associated with overuse of acute pain medication and further, where the patient specifically takes the medication prior to experiencing pain and experiences pain after the intake of acute pain medication, in order to treat the acute pain medication overuse disorder caused by the overuse of acute pain medication.

The intradermal administration of a pure botulinum toxin that has a molecular weight of about 150 kDa in order to treat an acute pain medication overuse disorder, as claimed, simply is not disclosed nor suggested by the combination of Schim (which does not teach the use of pure botulinum toxin (Office Action at page 3) with Johnson et al. (which does not disclose the use of the pure toxin for *any* headache treatments, let alone for treating an acute pain medication overuse disorder caused by overuse of acute pain medication, and even more particularly, does not disclose the *intradermal* administration of a pure botulinum toxin to treat acute pain medication overuse disorder, as claimed). Additionally, each of the instant dependent claims is also limited to the claimed intradermal administration of pure botulinum toxin, as well recite as additional limitations that are not disclosed in Schim and/or Johnson et al.

Thus, Johnson et al. does not disclose or suggest the use of pure botulinum neurotoxin in a method to treat any headache let alone an acute pain medication overuse disorder, and in particular by intradermal administration, and taking that Schim does not teach or suggest the use of pure botulinum toxin, it appears that the combination of these two references is based upon the instant

specification, a classic example of hindsight reconstruction. Respectfully, this is an improper and it is respectfully asserted that the Office has not met its initial burden of establishing a *prima facie* case of obviousness and it is requested that these rejections be withdrawn in light of the amendments and remarks made herein.

IV. Rejection of claims rejects claims 1-20 and 29 under 35 U.S.C. 103(a).

The Office Action rejects claims 1-20 and 29 under 35 U.S.C. 103(a) as unpatentable over Tepper et al. in view of Johnson et al. Applicants respectfully traverse this rejection.

As above, a reading of Tepper et al. reveals that (as stated in the Office Action at page 6) this reference does not teach the use of pure botulinum toxin. In this aspect, the disclosure of Tepper et al. discusses botulinum toxin administration in the preventative treatment of refractory headaches (treatment of refractory headaches in patients that are medication overusers as well as non-overusers). Tepper et al. does not teach or suggest methods for treating patients suffering from an acute pain medication overuse disorder, where the patient experiences pain after the intake of acute pain medication, as presently claimed. Also and accordingly, Tepper does not teach the use of pure botulinum toxin and further, Tepper does not teach or disclose administration according to the instantly claimed methods, which are all limited to the method step of local intradermal administration of a pure botulinum toxin having a molecular weight of about 150 kDa to a patient with acute pain medication overuse disorder to thereby treat the acute pain medication overuse disorder caused by the overuse of acute pain medication.

As above, the Office, in order to supplement this lack of disclosure/teaching of the use of a pure botulinum toxin having a molecular weight of about 150 kDa (Office Action, page 6), turns to and applies Johnson et al.'s disclosure, and combines its teachings with those of Tepper et al. However

and as stated above, Johnson et al.'s discussion of long shelf life of its pure botulinum toxin compositions or the lessening of the possibility of antibody formation after injection in a patient does not supplement the lack of teaching of Tepper et al. of local intradermal administration of a pure botulinum toxin having a molecular weight of about 150 kDa to the patient with acute pain medication overuse disorder to thereby treat the acute pain medication overuse disorder caused by the overuse of acute pain medication, where the patient specifically takes the acute pain medication prior to experiencing pain and experiences pain after the intake of acute pain medication, as claimed.

As above, the combination of Tepper et al. (which does not teach pure botulinum toxin) and Johnson et al. (which does not disclose the use of the pure toxin for *any* headache treatments, let alone for treating an acute pain medication overuse disorder caused by overuse of acute pain medication, and even more particularly, does not disclose the *intradermal* administration of a pure botulinum toxin to treat acute pain medication overuse disorder in a patient that takes the acute pain medication prior to experiencing pain and experiences pain after the intake of acute pain medication) appears to be the result of a classic hindsight reconstruction, where the combination of these two references is based upon the Applicants' own disclosure, which is clearly improper. Thus the instant independent claims are nonobvious over the cited references and additionally, each of the dependent claims also include limitations of the independent claims from which they depend, as well as additional limitations that are not disclosed in either Tepper et al and/or Johnson et al. and thus are also nonobvious over the cited referenced. Respectfully, the Office has failed to establish a proper *prima facie* case of obviousness for the instant claims and it is respectfully requested that this rejection be withdrawn.

V. Conclusion

All issues raised in the Office Action have been addressed. Reconsideration and allowance of claims 1-20 and 29 is respectfully requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, including fees associated with the Request for Continued Examination (RCE) and any fees associated with an extension of time to reply to the Office Action, and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/Claude L. Nassif/

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